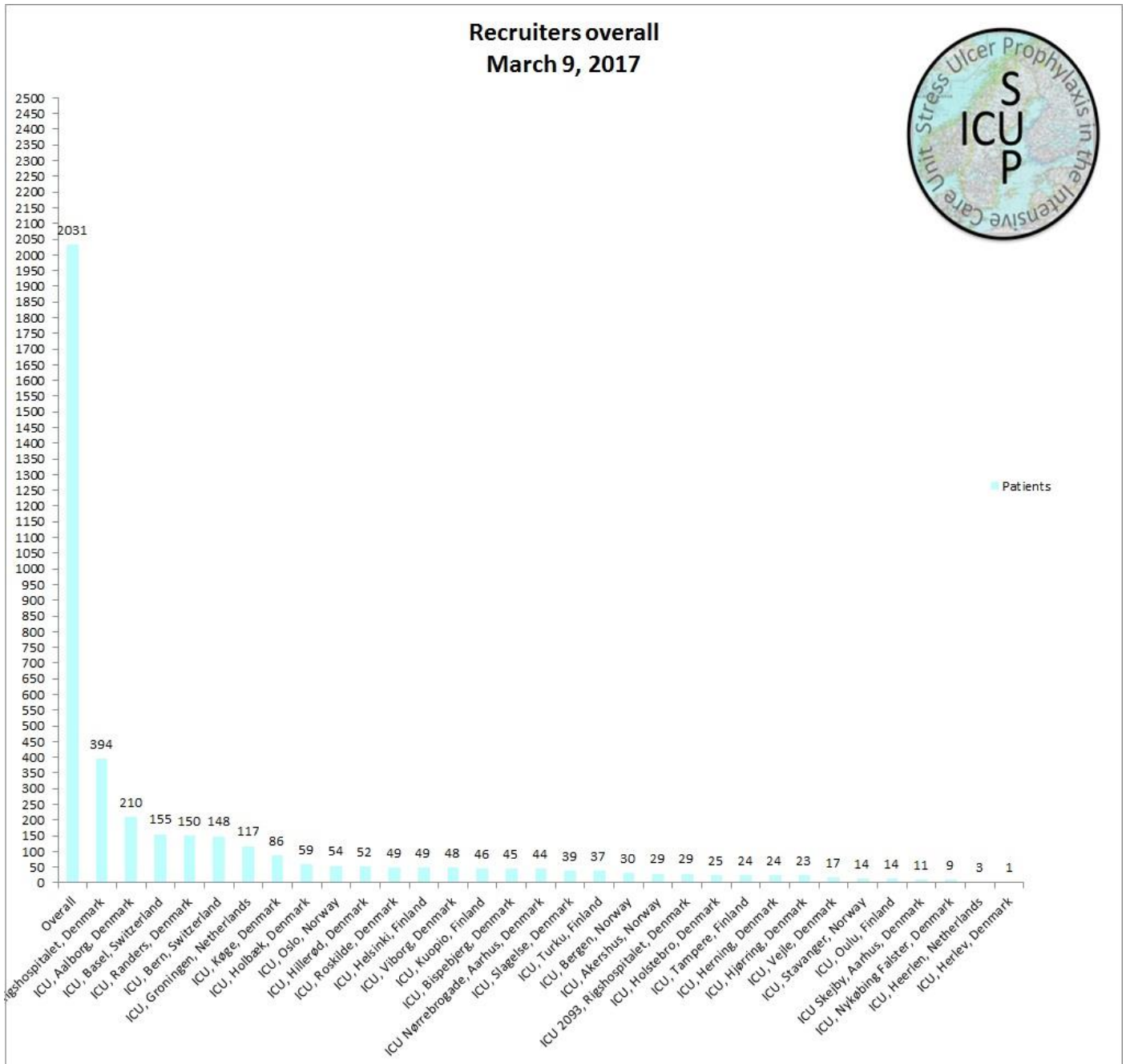




# Place in Site Master File #13

## SUP-ICU newsletter – March 2017



Thank you for your great commitment to the SUP-ICU trial.



## Status

Congratulations and thanks to all – we have passed **2000** randomised patients!

Since the previous newsletter more than 160 patients have been randomised, and we have now randomised 2031 patients (61%). Thirty-two sites in five countries are active.

You can follow the inclusion and the number of active trial sites at [www.sup-icu.com](http://www.sup-icu.com) (press F5 to refresh the page and get the updated status).

## New sites

Herlev Hospital, Denmark and Heerlen, Netherlands, have joined the trial – a warm welcome in SUP-ICU!

## Top recruiters

Top 5 overall recruiters in February were:

1. (Rigshospitalet 4131) (23)
2. Aalborg (22)
3. Basel (19)
4. Randers (14)
5. Århus NBG (9)

Congratulations to Aalborg for finishing as monthly top recruiter in February – 22 patients included in Aalborg in one month - very impressive! Basel and Randers continue to randomise patients at a steady state.

## Future active sites

Cardiff, Wales, will be joining the trial as the first UK site very soon. We look very much forward to welcoming the UK in SUP-ICU. Other UK sites are expected to follow. Italian sites are awaiting the final national approvals.

## Important information

- **IMPORTANT:** Please complete all data registration of patients randomised in the trial until January 20<sup>th</sup> 2017, including 90-day follow-up (when possible) to prepare for the first interim analysis of 1675 randomised patients (50%). Deadline for complete data registration, including 90-day follow-up, of these patients are **April 20<sup>th</sup> 2017**.
- All sites, including non-Danish sites, should download the 'Annual Safety report' (<http://www.cric.nu/sup-icu-annual-safety-report/>) – and archive this in the site master file #4.
- Please check-up on the status of previously completed 'follow-up'-forms - We have fixed an error in the eCRF and some forms may have returned to 'uncompleted'/'yellow'.
- BL37 (Baseline form): "*Highest Bilirubin in the 24 hours prior to randomisation? – If no value is obtained, write the first value from the 24-hour period after randomisation*": A lot of 'unobtainable'-values are registered in the baseline forms. Please take measures to obtain these values, e.g. by requesting it on inclusion if not already present, as we will otherwise get a lot of missing data

## Other

- In February the inclusion rate has dropped a bit. Please continue to systematically screen patients for inclusion.

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- Thank you very much for your commitment; please keep up the great work – less than 40% to go!

### **SUP-ICU hotline**

If you have any questions please send us an email ([soeren.marker.jensen.01@regionh.dk](mailto:soeren.marker.jensen.01@regionh.dk)) or contact the SUP-ICU hotline 24/7 (+45 3545 7450). If no one answers the phone, please **leave a message and your phone number** and we will call you back as soon as possible.

Please archive this newsletter in your Site Master File.



**Best regards**

**Søren, Anders, Carl and Morten**